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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,066	12/07/2001	John J. L. Simard	CTLIMM.21CP1C	8425

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
VANDERVEGT, FRANCOIS P	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,066	SIMARD ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 29-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 29-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 6-28 have been canceled.

New claims 29-36 have been added.

Claims 1-5 and 29-36 are currently pending.

Priority

1. Benefit claims under 35 USC § 120 must include a specific reference to the earlier filed (nonprovisional) application for which a benefit is sought. A "specific reference" requires: (1) the identification of the prior (nonprovisional) application by application number; and (2) an indication of the relationship between the nonprovisional applications (see USPTO Official Gazette Notice published March 18, 2003). The present application falls short of part (1) of the requirement because the attorney docket number is not an adequate identifier to comply with the requirement.

Accordingly, the priority claim to earlier filed applications is not granted and the earliest priority date to which the instant application is entitled is its actual filing date, which is December 7, 2001.

If the application is an application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a nonprovisional application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the reference to the prior application must be made during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, applicant must file a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) or (a)(6). The petition must be accompanied by: (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted); (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Election/Restrictions

2. Applicant's election without traverse of Group I, claims 1-5, in the reply filed on April 5, 2004 is acknowledged.

It is noted that Applicant has filed new claims 29-36 drawn to isolated T cells. The new claims are commensurate with the subject matter of Group I and will be examined as part of the elected Group.

3. Applicant asserts in the response filed April 5, 2004 that claim 1 is a linking claim that links the claims of Groups II and III to Group I. Applicant contends that the "provisional election is made with the understanding that upon allowance of linking claim 1, the restriction between the claims of Group II and Group III shall be withdrawn." It is noted, however, that Applicant has canceled all claims drawn to Groups II and III.

However, Applicant was notified in section 9 of the Restriction Requirement mailed March 5, 2004 regarding rejoinder practice. Specifically, Applicant was advised that, in order to retain the right to rejoinder, the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Applicant was further advised that failure to do so may result in a loss of the right to rejoinder. In canceling the claims drawn to Groups II and III, Applicant has failed to keep the method claims co-pending with the compound claims.

Accordingly, rejoinder of the method claims with compound claims that are ultimately found allowable may not be required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 and 29-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 29 and 30 are ambiguous and unclear in the recitation of "a first housekeeping epitope," "a first antigen" and "a first target cell." The multiple recitations of "first" render the claims indefinite because there is no indication of any second or additional elements related to the "first" elements in either the base claims or dependent claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 29, 30 and 33-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zajac et al (145 on form PTO-1449; Int. J. Cancer [1997] 71:491-496).

Zajac teaches isolated T cells that recognize the HLA-A2.1-restricted housekeeping epitope consisting of amino acid residues 27-35 of the MelanA tumor-associated antigen from melanoma target cells (Abstract and page 491, first column in particular)[claims 1, 3, 29, 30, 33-35]. Zajac teaches that tumor-infiltrating-lymphocytes (TILs) were isolated from melanoma patients were able to specifically lyse target cells (pages 492-493 and Figure 2 in particular). The TILs qualify as being "isolated from an immunized animal" because they were obtained from melanoma patients and were therefore "immunized" to the antigen by the presence of the tumor in their body [claim 5]. Zajac also teaches that peripheral blood lymphocytes from healthy donors that were primed *in vitro* with the peptide generated cytotoxic T lymphocytes (CTLs) that were able to specifically lyse target cells (pages 492-494 and Figure 3 in particular)[claim 4]. Zajac further teaches specific lysis of the target cells by the HLA-A2.1 restricted T cell lines HBL and D10 (Figures 2 and 3 in particular)[claim 2]. The prior art teaching clearly anticipates the claimed invention.

6. Claims 1-5, 29, 30, 33, 34 and 36 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kittlesen et al (79 on form PTO-1449; J. Immunol. [1998] 160:2099-2106).

Kittlesen teaches isolated T cell lines that recognize the HLA-A1-restricted housekeeping epitope consisting of the amino acid sequence KCDICTDEY of the tyrosinase tumor-associated antigen from melanoma target cells (Abstract and page 2100, first column in particular)[claims 1, 29, 30, 33, 34, 36]. Kittlesen teaches that the tyrosine reactive T cells are obtained from melanoma patients whose tumors express tyrosinase (paragraph bridging pages 2100-2101 in particular) and therefore qualify as being "isolated from an immunized animal" because they were obtained from melanoma patients and were therefore "immunized" to the antigen by the presence of the tumor in their body [claim 5]. Kittlesen further teaches that the T cell lines were enriched in vitro from polyclonal populations [claim 3] obtained

from melanoma patients by repeated rounds of stimulation with the peptide (page 2100, first column in particular) [claims 2, 4]. The prior art teaching clearly anticipates the claimed invention.

7. Claims 1-4, 29-32 and 35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Jager et al (75 on form PTO-1449; J. Exp. Med. [1998] 187:265-270).

Jager teaches isolated CD4+ T cell lines and an HLA-A2 restricted CTL clonal line that recognize housekeeping epitopes of the NY-ESO-1 cancer-testis tumor-associated antigen (Abstract and page 266, first column in particular)[claims 1-3, 29-32, 35]. Jager teaches that the NY-ESO-1 reactive T cells are obtained from PBL and a needle biopsy from a melanoma patient. Kittlesen further teaches that the T cell lines were enriched in vitro from polyclonal populations [claim 3] obtained from the melanoma patient by repeated rounds of stimulation with the peptide (page 266 in particular) [claims 2, 4]. The prior art teaching clearly anticipates the claimed invention.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. FPV
Patent Examiner
June 10, 2004

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
6/11/04